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510(K) SUMMARY

1. SUBMITTER:

Innovasive Devices, Inc.
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Contact: Eric Bannon, Vice President of Quality Assurance and Regulatory Affairs
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2. DEVICE:

Innovasive 2.8mm and 3.5mm ROC LF Suture Bone Fastener
Classification Name: Single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices ROC LF Suture Bone Fastener

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Innovasive Devices 2.8mm and 3.5mm Roc LF Suture Bone Fastener was the Innovasive Devices ROC Suture Bone Fastener, marketed by Innovasive Devices, Marlborough, MA.

4. DEVICE DESCRIPTIONS:

The ROC LF suture bone fastener implant tip portion consists of a shear pin, expander and sleeve. The expander and sleeve is fitted onto the shear pin component such that the expander component is located below the sleeve on the shear pin. As the shear pin is pulled up during the device deployment, the expander engages the sleeve. The expander is tapered such that it will fit into the sleeve component as the deployment action progresses. As the expander is drawn into the sleeve, the sleeve expands to make contact with the surrounding bone. This expanding sleeve results in the final fixation properties of the device. Once the expander is completely seated inside the sleeve, the shearing pin shears from the fastener assembly resulting in the device being fixated into the bone hole.

In addition to the Fastener, a stainless steel drill and drill guide is available to establish the proper hole in the bone for the Fastener along with an obturator, deployment handle and hole finder. All of the instrumentation except the Fastener

will be offered as reusable devices and can be autoclaved in the sterilization tray provided for this purpose.

The Fastener will be available as a sterile, single use device in both an open and arthroscopic version. Both sutured and sutureless versions will be marketed.

5. INTENDED USE:

The 2.8mm and 3.5mm ROC LF Suture Bone Fasteners are intended for the reattachment of soft tissue to bone for the following indications:

SHOULDER

1. Repair of rotator cuff tears
2. capsular instability
3. slap lesion repair
4. acromio-clavicular separation
5. capsule shift/capsulolabral reconstruction
6. biceps tenodesis
7. deltoid repair

KNEE

1. Extra-capsular repairs, and reattachment of medial collateral ligament, lateral collateral ligament, posterior oblique ligament, joint capsule closure.
2. Patellar ligament and tendon avulsion repairs.
3. Extra-capsular reconstruction, ITB tenodesis

ANKLE

1. Lateral instability
2. Medial instability
3. Achilles tendon reconstruction and repair
4. Mid-foot reconstructions

FOOT

1. Hallux valgus reconstruction

BLADDER NECK SUSPENSION

1. Bladder neck suspension for female urinary incontinence due to urethral hypermobility.

6. COMPARISON OF CHARACTERISTICS:

The Innovative Devices ROC Suture Bone Fastener is comprised of two polymer components, high density polyethylene and acetyl plastic. This device is used to secure suture in a predrilled hole in bone. It remains fixed in the bone through radial compression as the device is deployed. This remains true for all sizes of the device.

The ROC LF device consists of similar materials as the ROC fastener. It uses an expander fitted on a shear pin which is drawn up into an expanable sleeve. The sleeve expands as the expander is drawn up into it. The shear pin then shears resulting in the device being fixed into the bone site.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Cadaver study: Comparison of the ultimate holding strength in the humeral head and glenoid compared to the predicate device. The Innovative ROC LF Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate device.
2. Bone model testing: Comparison of the ultimate holding strength in the bone model compared to the predicate device. The Innovative ROC LF Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate device.